

Sterile Compounding Inspection Report  
Sterile Compounding Committee  
March 19, 2013



CALIFORNIA STATE  
BOARD OF PHARMACY

# Overview

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- ▶ Sterile Compounding Requirements for Resident and Non-Resident Pharmacies
- ▶ Total Number of Licensed Pharmacies by Type
- ▶ Recent Sterile Compounding Inspection Findings from 35 licensed pharmacies
- ▶ Recent Sterile Compounding Inspection Findings from 21 hospital pharmacies
- ▶ Recent FDA Inspection Findings from 4 pharmacies- Issues Identified with California Law



# Requirements for California Sterile Compounding License

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The following may compound injectable sterile drug products in California:

- ▶ A pharmacy that is specially licensed with the board as a sterile compounding pharmacy, or
- ▶ a pharmacy that is operated by an entity that is licensed by the board or the State Department of Health Services and has a current accreditation from the Joint Commission on Accreditation of Healthcare Organizations or another accreditation agency approved by the board. The following private accreditation agencies have been approved by the board:
  - ▶ Accreditation Commission for Health Care, Inc. (ACHC) through February 2014,
  - ▶ Community Health Accreditation Program (CHAP) through February 2014,
  - ▶ Det Norske Veritas (DNV) through July 2013,
  - ▶ Pharmacy Compounding Accreditation Board (PCAB) through February 2014, or
  - ▶ American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP) through February 2014.
- ▶ A license to compound injectable sterile drug products may not be issued until the location is inspected by the board and found to be in compliance with Article 7.5 of Chapter 9, of Division 2 of the Business and Professions Code and regulations adopted by the board.



# Requirements for Non-Resident Sterile Compounding License

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Effective July 1, 2003, a nonresident pharmacy may not compound injectable sterile drug products for shipment into California unless:

1. The nonresident pharmacy is licensed with the board as an injectable sterile drug compounding nonresident pharmacy, **OR:**
2. The nonresident pharmacy is operated by an entity that is licensed as a hospital, home health agency, or a skilled nursing facility, and has a current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or another accreditation agency approved by the board. The following private accreditation agencies have been approved by the board:
  - ▶ Accreditation Commission for Health Care, Inc. (ACHC) through February 2014,
  - ▶ Community Health Accreditation Program (CHAP) through February 2014,
  - ▶ Det Norske Veritas (DNV) through July 2013,
  - ▶ Pharmacy Compounding Accreditation Board (PCAB) through February 2014, or
  - ▶ American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP) through February 2014.



# State Pharmacy Licenses- March 2013

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Total California licensed pharmacies= 6898

License Type	Total
Community Pharmacy (PHE)	6409
Hospital Pharmacy (HPE)	489
Sterile Compounding (LSC)*	270
Centralized Hospital Packaging	0

\*LSC licensed is in addition to a community or hospital pharmacy license



# Non Resident Pharmacy Licenses- March 2013

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License Type	Total
Non-Resident Pharmacy	478
Non-Resident Sterile Compounding License	92

\*Sterile Compounding license is in addition to a pharmacy license

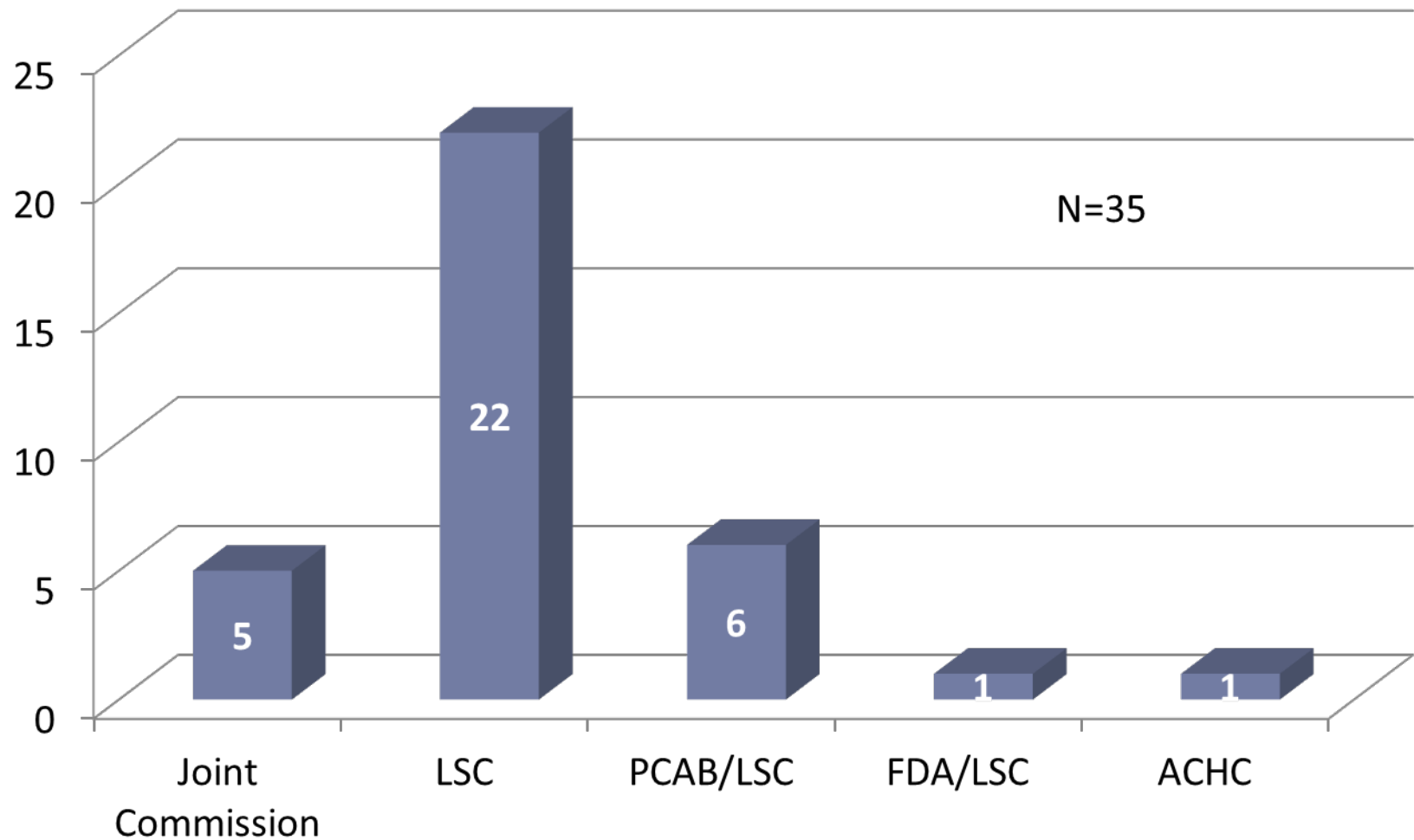




## Recent BOP Sterile Compounding Inspection Results

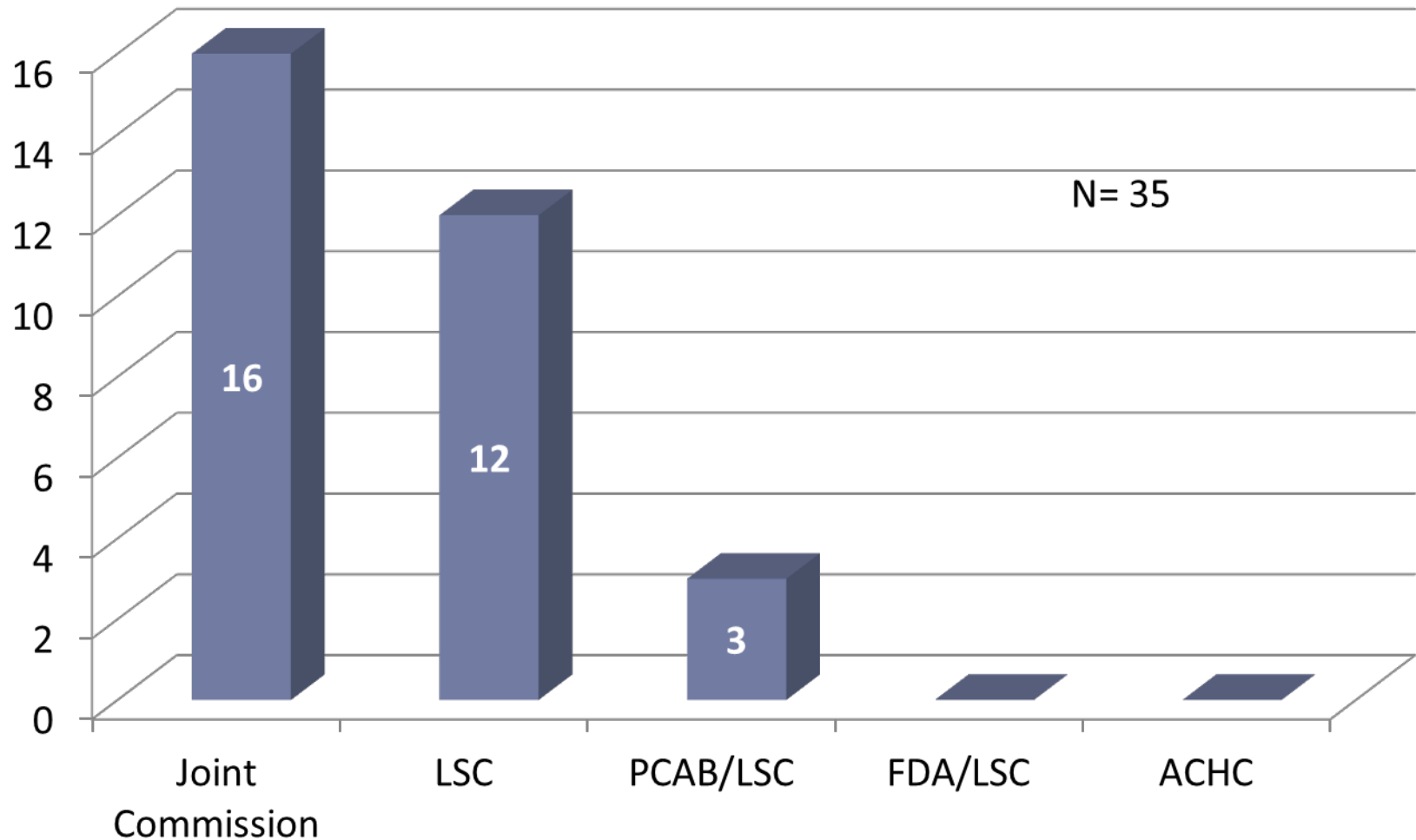
35 pharmacies – all located within California

# Recent Inspections- By Accreditation Type

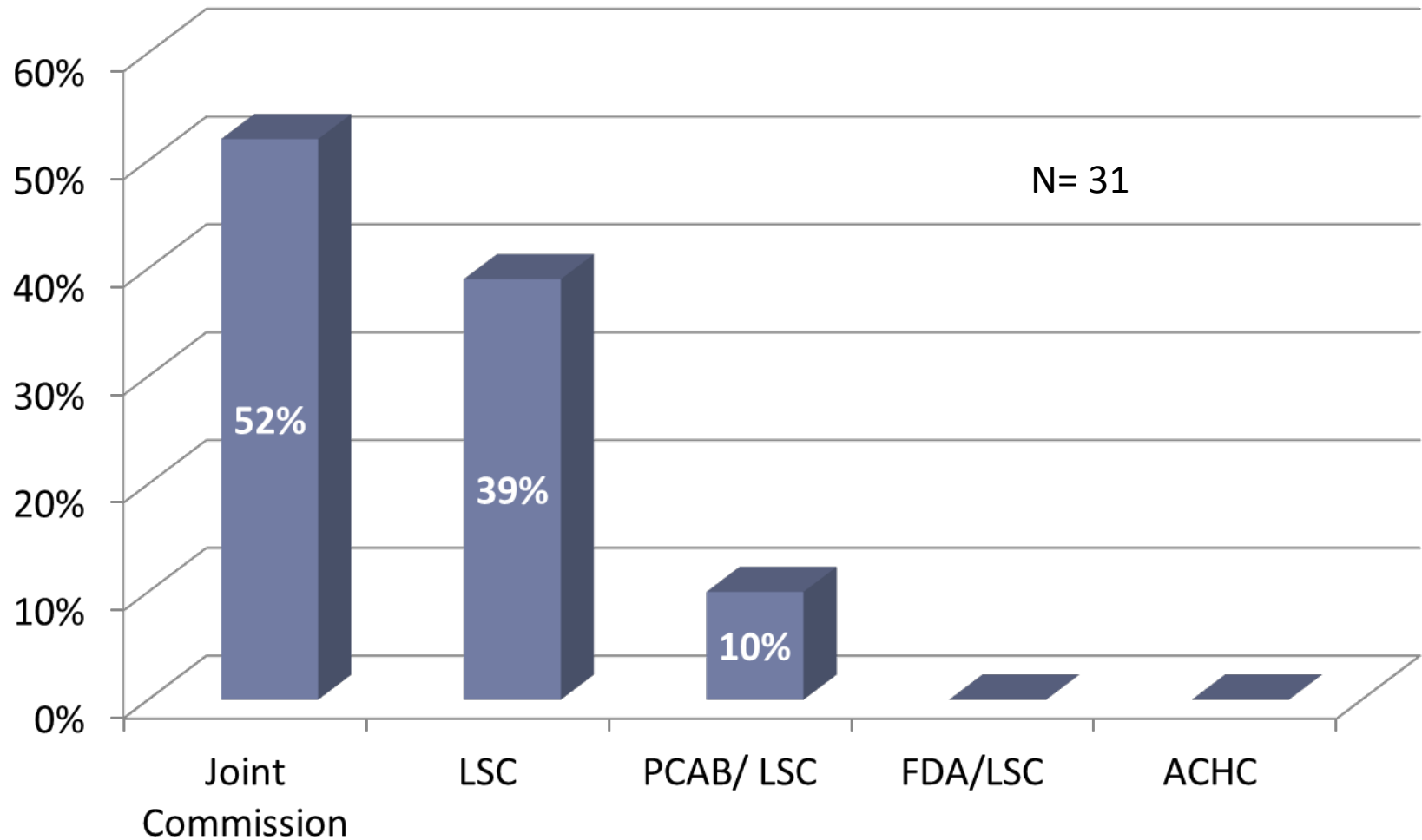




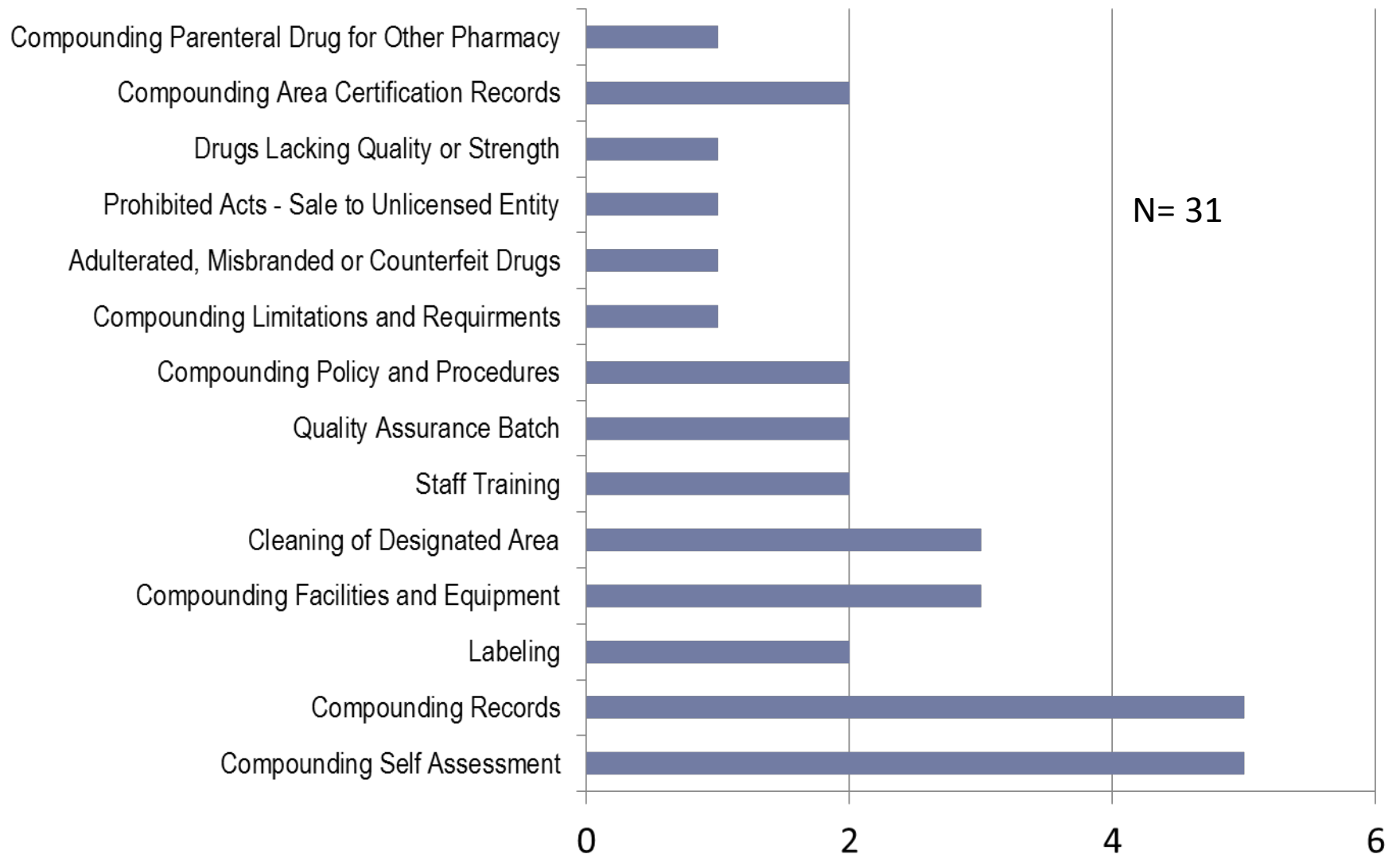
# Corrections Issued for Recent Inspections By Accreditation Type



# Total Corrections Issued Percentage By Accreditation Type



# Consolidated Inspection Report Citation Data



Survey Element N= 35		Total
Number with LSC License		29
Patient Type	Human/Animal	21/2
	Human & Animal	12
Self Reported to be USP 797 Compliant		30 / 5
Accredited		12
High Risk Compounding		21
Ships Compounded Product Out of State		13
Compounds Non Patient Specific Product		16
Hood Certification	3 month	1
	6 month	31
	12 month	3
Viable Air Counts		21
Surface Testing		11
Fingertip Testing		10
Sterility		30
Pyrogen		24

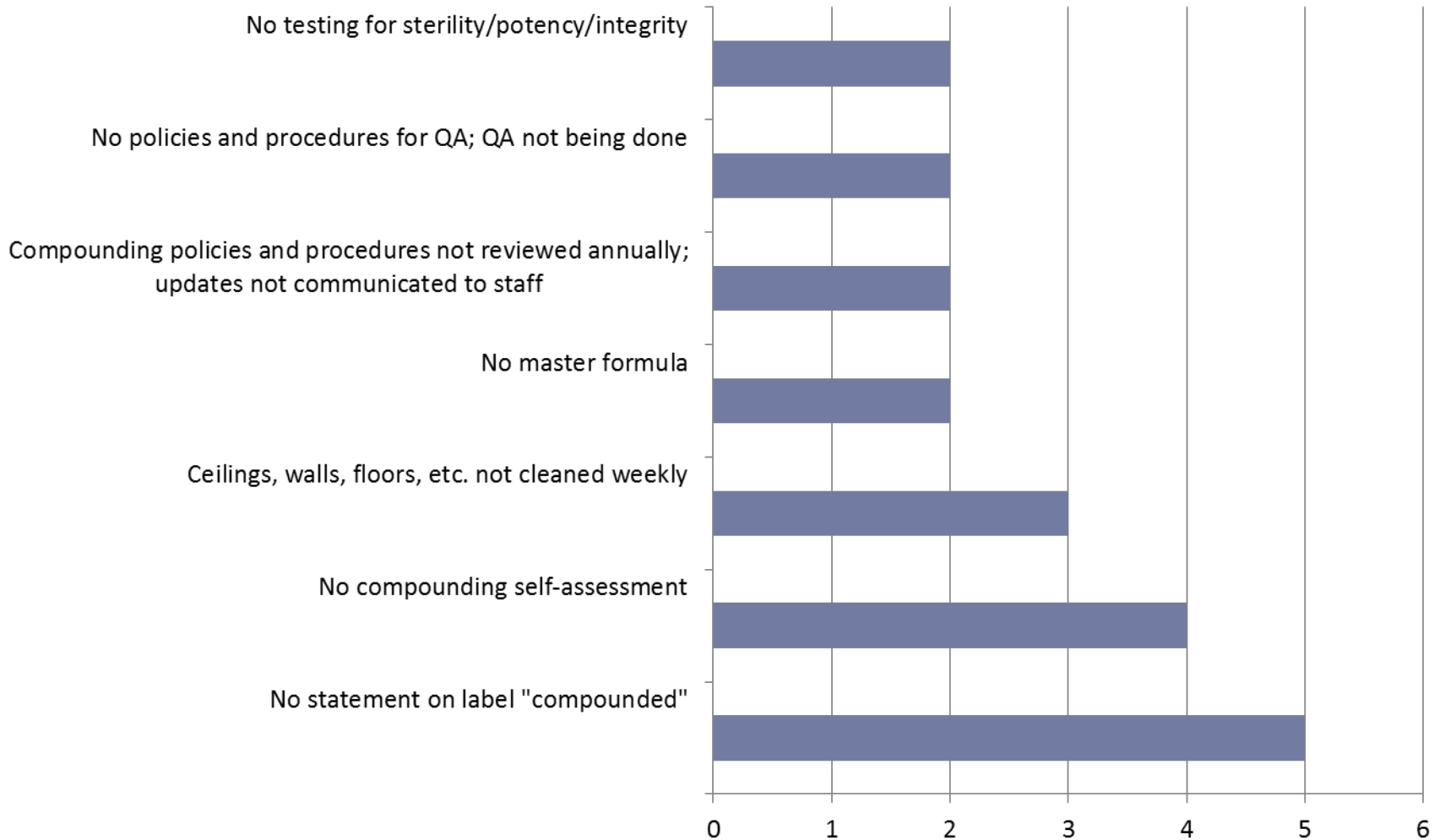
# State BOP Recent Hospital Pharmacy Inspections

21 Hospital Pharmacies

# Hospital Pharmacy Inspection Findings

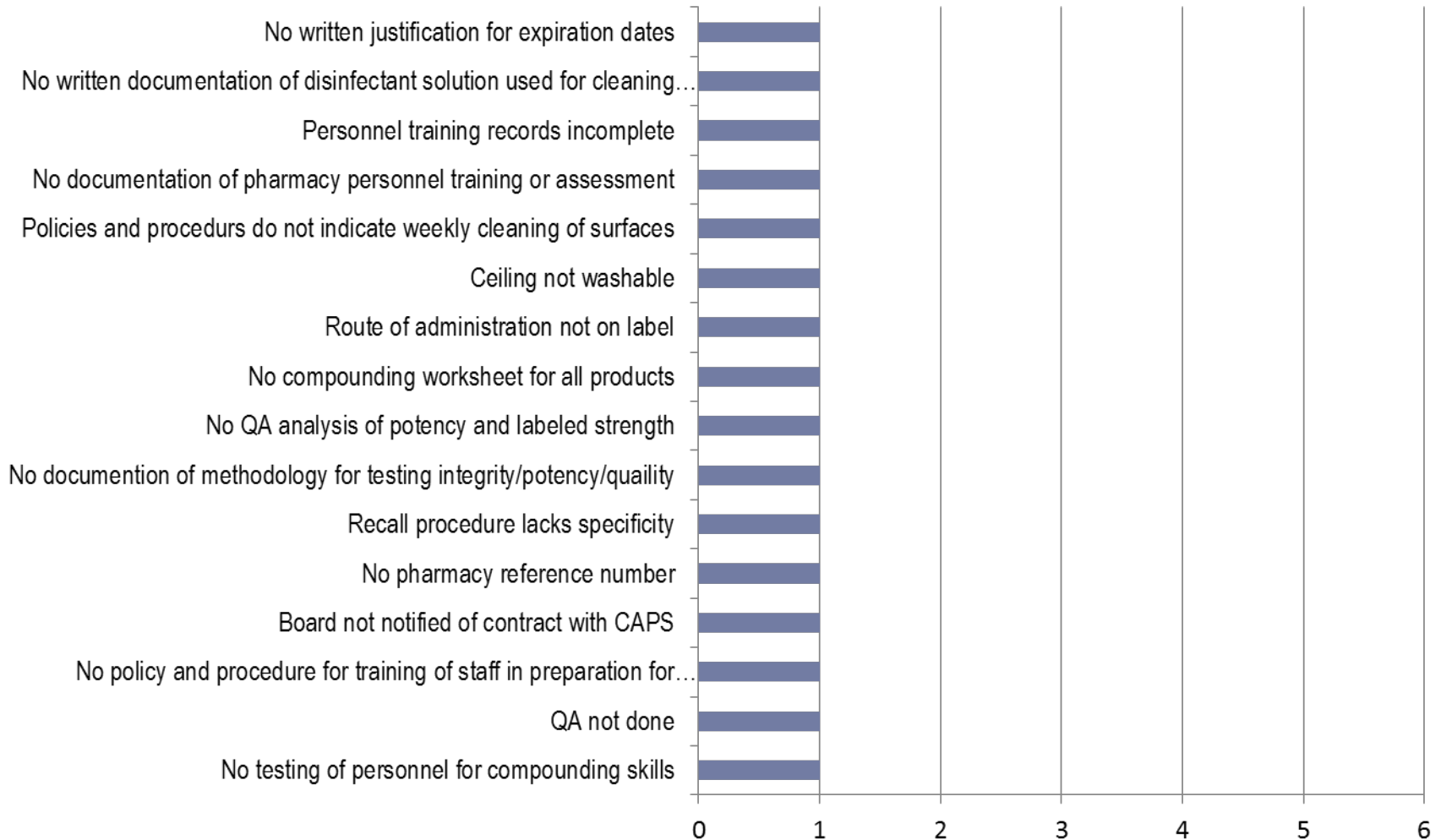
## Top 7 Findings

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# Hospital Pharmacy Inspection Findings

## Additional Findings





## Recent FDA Inspection Findings Items Identified with California law non-compliance

Four Independent Non-Resident Pharmacies Surveyed from  
Target 30 List



Count of Findings	Description of Findings	Notes
3	Batch produced sterile injectable products compounded from one or more non-sterile ingredients subject to end product testing	All products not tested, or partially tested or product not tested in final container
1	Expiration date may not be longer than the shortest expiration date of ingredient	
1	No sterile product shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria.	Viable air samples from hood exceeded action levels but no action taken
1	Expiration dating	90 day dating for all intrathecal medication without adequate stability data tested with stability-indicating methods)
1	Compounding record - documentation of equipment	
1	Compounding record - documentation of manufacturer and lot number	

